

May 26, 2004

Thomas M. Gray, M.S., D.A.B.T.
Senior Toxicologist
The American Petroleum Institute
Petroleum HPV Testing Group
1220 L Street N.W.
Washington, DC 20005

Dear Dr. Gray:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for the Asphalt Category posted on the ChemRTK HPV Challenge Program Web site on January 20, 2004. I commend The American Petroleum Institute Petroleum HPV Testing Group for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Petroleum HPV Testing Group advise the Agency, within 90 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Asphalt Category

Summary of EPA Comments

The sponsor, the Petroleum HPV Testing Group, submitted a test plan and robust summaries to EPA for the Asphalt Category dated December 15, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 20, 2004.

EPA has reviewed this submission and has reached the following conclusions:

1. Category Justification. EPA agrees that grouping these substances into a single category is appropriate on the basis of similar physicochemical properties and production processes. Also, limited data and other information support the conclusion that environmental fate, health effects and ecotoxicity are not expected to vary significantly across category members.
2. Physicochemical Properties. EPA agrees that no further testing is necessary for these endpoints, but recommends that the submitter include vapor pressure and water solubility data for polycyclic aromatic compounds (PACs) present in asphalt.
3. Environmental Fate. EPA agrees that no further testing is necessary for these endpoints, but recommends that the submitter provide a range of estimated atmospheric half-lives of representative components.
4. Health Effects. Adequate data are available for the acute and repeated-dose toxicity endpoints for the asphalt category and for the genetic toxicity endpoints for whole asphalt for the purposes of the HPV Challenge Program. EPA agrees with the submitter's plan to conduct a combined reproductive and developmental toxicity screening test on asphalt fume condensate. In addition, the submitter needs to provide robust summaries on chromosomal aberrations of asphalt fume condensate and to address deficiencies in the robust summaries.
5. Ecological Effects. EPA agrees that adequate data are available for these endpoints.

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.

EPA Comments on the Asphalt Category Challenge Submission

Category Definition

Asphalts are complex mixtures of paraffinic, naphthenic, and aromatic hydrocarbons and are the residual components resulting from the non-destructive distillation of crude oil. Components of asphalts include asphaltenes, resins, aromatic oils, and saturated oils; they have high carbon-to-hydrogen ratios with carbon numbers predominantly greater than C25, boiling point ranges >400°C, high viscosity, and negligible vapor pressure. Asphalts may also include low levels of 3- to 7-ring polycyclic aromatic compounds (PACs), naphthalenes, substances with nitrogen, sulfur, and oxygen, and metals such as vanadium, nickel, and iron. The proportion of these substances in asphalts varies with the source of the crude oils and the processes used to manufacture the asphalts. When asphalts are heated to facilitate paving or roofing applications, the lighter, more volatile components are distilled into the atmosphere. They condense as they cool, forming small droplets of liquid known as asphalt fume condensate.

The Asphalt Category is defined by the following six CAS Numbers: asphalt (penetration or hard) (CAS No. 8052-42-4); vacuum residues (CAS No. 64741-56-6); raffinates, residual oil decarbonization (CAS No. 64742-07-0); petroleum resins (CAS No. 64742-16-1); residues, hydrodesulfurized vacuum (CAS No. 64742-85-4); and asphalt, oxidized (CAS No. 64742-93-4). Data were also submitted for asphalt fumes (CAS No. 8052-42-4, according to the National Library of Medicine's ChemID Plus database). The category does not include asphalts that have been mixed with other oils, heavy distillates, or additives.

Category Justification

The available data on physicochemical properties, environmental fate and toxicity support the grouping of these substances into a single category. However, the potential adverse effects of toxic metals, if present, remain uncertain. The submitter stated that one category member, asphalt (CAS No. 8052-42-7), contains small amounts of various metals such as nickel, iron, or vanadium. The test plan did not indicate if metals are expected to be present in other category members.

Despite limited measured data presented in the test plan, the available information indicates that members of the asphalt category are expected to have similar boiling points, vapor pressures, log K_{ow} values (>10), and water solubilities. The limited environmental fate data submitted also support the grouping of these asphalts under one category. Upon release to the environment, asphalts are expected to distribute similarly because of their low volatility and limited water solubility. Asphalts are expected to be resistant to biodegradation, and those components that are soluble in water are expected to be resistant to hydrolysis.

The submitter noted that a key element to consider when compositionally analyzing this category for certain toxicity endpoints is the percentage of 3- to 7-ring PACs. Although PAC concentrations are listed in several of the robust summaries on asphalt fume condensate and are aggregated along with naphthalene in the robust summary on asphalt for water solubility, no other data on PAC concentrations in category members were available to determine if a pattern existed with respect to 3- to 7-ring PACs and toxicity. The submitter stated in the test plan that the content of known carcinogenic PACs in asphalts is in the low parts per million range. In addition, the levels of 3- to 7-ring PACs are expected to be low in all category members considering the processes used to manufacture these substances. Also, the high molecular weights and similar hydrocarbon distributions among asphalt category members support the conclusion that the toxicity of asphalts in general is not expected to vary significantly across members. Therefore, grouping these substances into a single category is appropriate.

With regard to asphalt fume condensate, the submitter stated in the test plan that fumes generated experimentally at high temperatures are more likely to contain carcinogenic PACs than fumes generated at the lower temperatures usually seen in field samples. Therefore, generating conditions are expected to significantly affect toxicity.

No aquatic toxicity data on asphalts were submitted. However, based on limited water solubility, high log K_{ow} , similar hydrocarbon composition, and low levels of other constituents that may affect toxicity, grouping these substances into a single category is appropriate.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter for melting point, boiling point, and partition coefficient are adequate for the purposes of the HPV Challenge Program.

Vapor Pressure. The submitter stated that because asphalts contain complex hydrocarbon mixtures with molecular weights ranging from 500-2000 and carbon numbers predominantly higher than C25, vapor pressures are negligible. EPA agrees that the majority of compounds in this category have negligible vapor pressures under ambient temperatures. However, asphalts contain low levels of PACs which can volatilize as materials are heated, as commonly occurs in roofing or paving applications. EPA does not recommend further testing, but suggests that the submitter provide in the robust summary a range of vapor pressures for potentially volatile asphalt components.

Water solubility. The submitter did not provide solubility data, but presented data on asphalt samples that had been placed in acidic water to measure levels of PAC components leached from the samples. In all cases, levels of PACs in leachate were low, usually in the parts per trillion range. EPA does not recommend further testing, but suggests that the submitter include in the robust summary the water solubilities of PACs detected in leachate samples or a range of water solubilities for each of the PACs classes identified.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

EPA agrees with the stability in water information provided by the submitter. EPA agrees with the submitter's proposal to provide technical discussions for biodegradation and fugacity.

Photodegradation. The submitter noted that the majority of hydrocarbons in asphalts are not susceptible to direct photolysis, since they do not have functional groups that absorb sunlight greater than 290 nm. However, it was also noted that certain aromatic and unsaturated compound members have the potential to undergo photolysis because they absorb light in the environmental UV region. The submitter reasoned that since asphalts contain high molecular weight hydrocarbons, partitioning to the atmosphere is not important. EPA agrees that the majority of components will not partition to air. However, asphalts are often heated during their application and use in roofing or paving materials and the low levels of PACs in these materials can volatilize. EPA suggests that the submitter provide a range of photodegradation half-lives for volatile PAH components in asphalts.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for the acute and repeated-dose toxicity endpoints for the asphalt category for the purposes of the HPV Challenge Program. The submitter needs to address deficiencies in the robust summaries.

Genetic toxicity. Adequate data are available for genetic toxicity (gene mutations and chromosomal aberrations) for solid asphalt (vacuum residue) and for gene mutations for asphalt fume condensate. Adequate data may be available for chromosomal aberrations for asphalt fume condensate based on the test plan discussion of a number of *in vitro* and *in vivo* chromosomal aberration (including micronucleus) assays (Qian *et al.*, 1996, 1999; Reinke and Swanson, 1993; Reinke *et al.*, 2000; Ma *et al.*, 2002) and a human study (Jarvholm *et al.*, 1999) mentioned on page 14 of the test plan. The submitter needs to provide full robust summaries for one or more of these studies to satisfy the chromosomal aberrations endpoint for asphalt fume condensates. Alternatively, the submitter may provide a robust summary for the micronucleus evaluation testing being conducted by Fraunhofer ITA (2002b) as part of a 2-year inhalation bioassay in rats on bitumen fumes (page 15, test plan).

Reproductive/developmental toxicity. EPA agrees with the submitter's plan to conduct a combined reproductive/developmental toxicity screening test on asphalt fume condensate following OECD TG 421 and recommends using fumes generated under conditions that maximize the level of PACs to represent a worst-case scenario.

Ecological Effects (fish, invertebrates, and algae)

EPA agrees with the use of analog data to satisfy the ecological effects endpoints for the asphalt category. The analog data provided are considered worst-case scenario, in that asphalt category members are more water-insoluble than the analogs. Therefore, asphalt category members are not likely to show adverse acute or chronic ecological effects in aquatic species. One limitation of the analog data, however, is that all aquatic tests referenced were performed using water-accommodated fractions (WAF) rather than measured data using HPLC analytical or equivalent techniques.

Specific Comments on the Robust Summaries

Health Effects

Acute toxicity. Although the acute inhalation assay (OECD TG 403) on fumes generated from a sample of bitumen condensate is considered adequate, the submitter needs to indicate whether the administered concentration, 100 mg/m³, is close to the maximum achievable concentration.

Repeated-dose toxicity. In two 28-day dermal toxicity studies, rabbits were exposed to two asphalt samples for 6 hours per day but only for 3 days per week. OECD TG 410 specifies 6 hours per day and 7 days per week, although 5 days per week is acceptable. Also, a No-Observed-Adverse-Effect-Level (NOAEL) was not achieved at any dose level in these studies and the presence of an encephalitozoon infection may have confounded test results. EPA recommends changing the reliability rating from “1 - Reliable without restriction” to “2 - Reliable with restrictions.” In addition, the highest dose listed in the table of the total weight gain results (page 18/45) should be 2000 mg/kg/day instead of 200 mg/kg/day.

Genetic toxicity. In the robust summaries for two bone marrow cytogenetic assays (Refs. 7 and 8), the units for doses listed in the tables should be g/kg/day instead of mg/kg/day.

Followup Activity

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.